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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,532

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Pradip Mukerji

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EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,532

Applicant(s)

MUKERJI ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) 3,4,10,11 and 17-25 is/are withdrawn from consideration.
5) ☒ Claim(s) 14-16 is/are allowed.
6) ☒ Claim(s) 1,2,5-9,12 and 13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040322 & 20050321.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION*Election/Restrictions*

Applicant's election in the reply filed on 13 April 2006 of the invention of Group 1 comprising claims 1, 2, 5-9 and 12-16 drawn to a polynucleotide encoding a polypeptide comprising the amino acid sequence of the *T. aureum* ORFA polyketide synthase PKS set forth in SEQ ID NO:10, to expression vectors and recombinant host cells comprising the encoding a polynucleotide, and to a method of use thereof in making the encoded PKS is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Amendments

Applicant's Amendments filed on 26 January 2004 and 13 April 2006 have been entered, providing a Sequence Listing in printed and electronic forms and amending claims 5, 8, 9, 12, and 14. Thus claims 1-25 remain in the application of which claims 3, 4, 10, 11, and 17-25 are withdrawn from further consideration by the examiner as drawn to a non-elected invention.

Priority

The instant application has the priority of its 15 July 2003 United States filing date.

Information Disclosure Statement

Applicant's Information Disclosure Statement [IDS] filed with the application on 15 July 2003 is hereby acknowledged.

Claim Objections

Claims 9, 12, and 16 are objected to because of the following informalities: The genus name *Thraustochytrium* is misspelled in claim 9, there is no conjunction between

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the end of clause (b) and the beginning of clause (c) in claim 12, and, in claim 16, the proper form of the indefinite article required before the word "eukaryotic", which begins with a vowel, is "an". Appropriate correction is required.

Objection to the Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at line 32 of page 12. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 5-9 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12-16 are not affected by this rejection because they require the use or the incorporation of the disclosed polynucleotide of SEQ ID NO:8. None of claims 1, 2, 8 or 9, however, requires any particular function or activity of a "polypeptide" encoded by a polynucleotide of claims 1 and 2 and the members of the genera of polynucleotides of claims 1 and 2 need not be related to the nucleic acid sequence of SEQ ID NO:8 either by codon degeneracy or by the capacity of being detected utilizing the hybridization and wash conditions set forth at pages 49 and 50 of the specification. While claims 5-7 require that a claimed polynucleotide encode a polyketide synthase, they also fail to require that the members of the genera of polynucleotides be related to the nucleic acid sequence of SEQ ID NO:8 either by codon degeneracy or by the capacity of being

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detected utilizing the hybridization and wash conditions set forth at pages 49 and 50 of the specification. The specification fails to exemplify or describe the isolation or the preparation of the divergent polyunsaturated fatty acid-polyketide synthases encoded by the polynucleotides of claims 1, 2 and 5-9 or such encoding polynucleotides where an encoded proteins protein differ at as much as 35% of the positions in the sequence of SEQ ID NO:10, i.e., by alteration at as many as 1,020 amino acid positions. Neither the claims nor the specification describe where any amino acid sequence differences occur, nor what the differences might be, and the specification does not otherwise disclose or suggest that any particular region or regions encompassing 1,020 amino acids of an encoded polypeptide is/are unnecessary for maintenance of a useful activity and may be removed from SEQ ID NO:10. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993).

The specification furnishes no relevant identifying characteristics of a polynucleotide that encodes either a featureless polypeptide or polyketide synthase that diverges from the amino acid sequence of SEQ ID NO:10 at as many as 1,020 positions and nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the structure of any of these undisclosed, generic, polynucleotides o provide the public with identifying "characteristics [that] sufficiently distinguish [them] from other materials". *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structure, or other properties, of the generic polynucleotides of claims 1, 2 and 5-9.

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Claims 1, 2 and 5-9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the preparation of polynucleotides that will hybridize to SEQ ID NO:8 under the conditions described and pages 9 and 50 of the specification and that encode a polyunsaturated fatty acid polyketide synthase, does not reasonably provide enablement for the preparation of polynucleotides that encode a polypeptide 65% identical to SEQ ID NO:10 or that are 70% identical to SEQ ID NO:8 and encode a polypeptide with no particular function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use] the invention commensurate in scope with these claims.

Claims 1, 2 and 5-9 contemplate an arbitrary assignment of any or all of codon substitutions, additions or deletions in the polynucleotide of SEQ ID NO:8 to change its coding capacity so that an encoded product diverges from the 2,915 amino acid sequence of SEQ ID NO:10 at as many as 1,020 positions. Yet the specification cannot support introduction of such a large number of alterations in the amino acid sequence of SEQ ID NO:10 such that an encoding polynucleotide would encode anything useful, in the case of claims 1, 2, 8 and 9 or encode a divergent polyketide synthase, in the case of claims 5-7. Indeed, neither the prior art made of record herewith nor Applicant's specification can identify, taken together, even a few amino acids in the sequence of the polyunsaturated fatty acid polyketide synthase that might be altered, nor teach the nature of an alteration that may be made, which permits a resulting polypeptide to function as a polyunsaturated fatty acid polyketide synthase, the only activity disclosed for SEQ ID NO:10. It is well settled that 35 U.S.C. § 112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (discussing eight factors relevant to analysis of enablement). Applying the factors discussed in *Wands*, to Applicant's disclosure, it is apparent that:

- a) the specification lacks adequate, specific, guidance for altering the amino acid sequence of the polyunsaturated fatty acid-polyketide synthase of SEQ ID NO:10 by preparing variants of SEQ ID NO:8 to the extent recited in the claims,

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- b) the specification lacks working examples wherein a polyunsaturated fatty acid-polyketide synthase of SEQ ID NO:10 is altered by preparing variants of SEQ ID NO:8 to the extent recited in the claims,
- c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,
- d) unpredictability exists in the art where no members of the class of polyunsaturated fatty acid-polyketide synthases represented by the amino acid sequence of SEQ ID NO: 10, have had as many as 1020 amino acids identified for concurrent modification by preparing variants of their encoding nucleic acid sequences.

Thus the scope of subject matters in claims 1 and 2 and claims depending therefrom embraced by the phrases, "at least 65% . . . identity" and "at least 70% . . . identity", is unsupported by the present specification even if taken in combination with teachings available in the prior art.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite because it is an incomplete statement of the intended method where, in addition to the lack of a conjunction such as "and" between clauses (b) and (c), the claim does not indicate that the intended production is accomplished by the recitation of a closing statement such as "whereby the polyketide synthase is produced". The artisan and the public seeking to determine the meets and bounds of the intended subject matter cannot know whether or not some further, necessary, procedure or step is required and amending the claim to indicate that the process includes all of its essential steps will overcome this rejection, which also affects claim 13 that depends from claim 12 but fails to rectify its ambiguity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Metz et al., US 2002/0194641, made of record with Applicant's Information Disclosure Statement.

This rejection is required because the recitations, "or fragment thereof", in both of claims 1 and 2 permit any fragment of an amino acid sequence of a polyunsaturated fatty acid-polyketide synthase, and any fragment of its encoding nucleic acid sequence, to be compared with any region of, respectively, SEQ IDs NOs:10 and 8 and the specification itself identifies no boundaries, e.g., by position numbers, for any particular fragment(s) of either SEQ IDs NOs:8 or 10. Metz et al. disclose in their SEQ IDs NOs:2 and 1 the amino acid sequence of, and a polynucleotide encoding, a polyunsaturated fatty acid-polyketide synthase wherein numerous fragments of the amino acid sequence and the encoding nucleic acid sequence meet the limitations of claims 1 and 2, see, e.g., the region between positions 46 and 1437 of SEQ ID NO:1 of Metz et al. which shares greater than 70% identity with the corresponding region of SEQ ID NO:8 herein and encodes an amino acid sequence that shares greater than 65% identity with the amino acid sequence region from position 103 through 565 of SEQ ID NO:10 herein, meeting the limitations of claims 1 and 2. The disclosure of Metz et al. also meets the limitations of claims 5-7 because Metz et al. disclose that their SEQ ID NO:1 encodes a functionally active polyketide synthase capable of producing, see paragraph 0051, eicosapentaenoic acid or docosahexaenoic acid when expressed in a host cell.

Allowable Subject Matter

While claims 12 and 13 are rejected hereinabove under 35 U.S.C. § 112, second paragraph, claims 12-16 are allowable over the prior art made of record herewith which fails to disclose or teach the isolation or preparation of a polynucleotide capable of

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encoding a polyunsaturated fatty acid-polyketide synthase having an amino acid sequence that is encoded by a polynucleotide comprising the nucleic acid sequence of SEQ ID NO:8. The amino acid sequence of the *Schyzochytrium* polyunsaturated fatty acid-polyketide synthase commonly disclosed in SEQ IDs NOs:2 of Metz et al., US 2002/0194641, US 2004/0235127, and WO 2002/83870, all made of record herewith, is the closest prior art but this amino acid sequence shares only 54.2% sequence identity with SEQ ID NO:10 herein between positions 91 and 2915, inclusive, wherein the most significant divergence is a relative insertion of 91 amino acids in the polypeptide of Metz et al. between positions 1856 and 1857 of SEQ ID NO:10 herein. Thus claims 14-16 are indicated as allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
20 June 2006


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER